UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,582	08/25/2000	Clint Ashford	018624	5782

7590 01/03/2006

Michael E Dergosits Esq
Dergosits & Noah LLP
Suite 1450 Four Embarcadero Center
San Francisco, CA 94111

EXAMINER	
PASS, NATALIE	

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/648,582	ASHFORD ET AL.	
	Examiner	Art Unit	
	Natalie A. Pass	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2005 and 15 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,7-9,16,17 and 31-55* is/are pending in the application.

4a) Of the above claim(s) *31-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7-9,16,17 and 55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendments filed 3 October 2005 and 15 August 2005. Claims 1-3, 7-9, 16-17, and 55 have been amended. Claims 4-6, 10-15, 18-30, 56-58 have been cancelled. Claims 31-54 have been withdrawn. Claims 1-3, 7-9, 16-17, and 55 remain pending.

Specification

2. The amendment filed 3 October 2005 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. "New matter" constitutes any material which meets the following criteria:

a) It is added to the disclosure (either the specification, the claims, or the drawings) after the filing date of the application, and

b) It contains new information which is neither included nor implied in the original version of the disclosure. This includes the addition of physical properties, new uses, etc. The added material which is not supported by the original disclosure is as follows:

- "adjusting the initial baseline value by factoring in cost offsets due to inflation and technological advances to establish a prospective cost for the decided course of treatment," as disclosed in claim 1, lines 17-18,
- "by factoring in one or more historically derived severity factors to derive an adjusted baseline value," as disclosed in claim 1, lines 19-20;

- "adjusted baseline value," as disclosed in claim 1, line 21;
- "for purposes of improving utilization of healthcare services in the decided course or treatment relative to utilization of healthcare services quantified by the initial baseline value [...]" as disclosed in claim 1, lines 25-27;
- "the decided course of treatment is selected from the group consisting of diagnostic tests, prescribed drugs, practitioner office visits professional fees, equipment operating costs, and medical procedures," as disclosed in claim 2, lines 4-7;
- "wherein the healthcare services comprise at least one of diagnostic tests, drug prescriptions, subsequent hospital visits and additional practitioner diagnosis," as disclosed in claim 2, lines 7-8;
- "wherein the initial baseline value is derived from historical data relating to normal operating policies of the insurance company," as disclosed in claim 3, lines 4-6;
- "the severity factors include at least one of the age of the patient, pre-existing conditions of the patient, comorbidity effects, drug interactivity, presence of diagnosis codes and defining procedures," as disclosed in claim 7, lines 5-7;
- "the process of adjusting the initial baseline value by factoring in one or more historically derived severity factors comprises applying one or more business rules quantifying how the severity factors affect treatment costs for the condition [...]"as disclosed in claim 9, lines 2-4;
- "means for adjusting the initial baseline value by factoring in cost offsets due to inflation and technological advances to establish a prospective cost for the decided course of treatment," as disclosed in claim 55, lines 16-18; and

- "by factoring in one or more historically derived severity factors to derive an adjusted baseline value," as disclosed in claim 55, lines 18-19.

In particular, Applicant does not point to, nor was the Examiner able to find, any support for this newly added language within the specification as originally filed on 25 August 2000. As such, Applicant is respectfully requested to clarify the above issues and to specifically point out support for the newly added limitations in the originally filed specification and claims.

Applicant is required to cancel the new matter in the reply to this Office Action..

3. If Applicant continues to prosecute the application, revision of the specification and claims to present the application in proper form is required. While an application can, be amended to make it clearly understandable, no subject matter can be added that was not disclosed in the application as originally filed on 25 August 2000.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Newly amended claims 1 and claims 2-3, 16-17, 7-9, 55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(A) Independent claims 1 and 55 and dependent claims 2-3, 7, 9 recite limitations that are new matter, as discussed above, and are therefore rejected.

(B) Claims 8, 16-17, incorporate the features of independent claim1, through dependency, and are also rejected.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the m3anner in which the invention was made.

7. Claims 1-3, 7, 16, 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler et al., U.S. Patent Number 5, 324, 077 in view of Bitran, et al, Provider Incentives and Productive Efficiency in Government Health Services document, September, 1992. URL: <http://www.phrplus.org/Pubs/hfsmar1.pdf>, hereinafter known as Bitran for substantially the same reasons as in the previous Office Action (paper number 03242005). Further reasons appear hereinbelow.

NOTE: The following rejections assume that the subject matter added in the 3 October 2005 amendment are NOT new matter, and are provided hereinbelow for Applicant's consideration, on the condition that Applicant properly traverses the new matter objections and rejections made in sections 2-5 above in the next communication sent in response to the present Office Action.

(A) Claim 1 has been amended to include the recitation of

- "[...] creating an initial baseline value related to treatment of the condition [...]" at line 7;
- "[...] along with an associated cost quantified by the initial baseline value [...]" at line 10;
- "[...] adjusting the initial baseline value by factoring in cost offsets due to inflation and technological advances to establish a prospective cost for the decided course of treatment, and by factoring in one or more historically derived severity factors to derive an adjusted baseline value [...]" at lines 17-20; and
- "[...] for purposes of improving utilization of healthcare services in the decided course or treatment relative to utilization of healthcare services quantified by the initial baseline value [...]" at lines 25-27.

As per these new limitations, Kessler and Bitran teach a method as analyzed and discussed in the previous Office Action (paper number 03242005) further comprising

creating an initial "dollar limit" (reads on "baseline value") related to treatment of the condition (Kessler; column 13, lines 15-33);

along with an associated cost quantified by the initial baseline value (Kessler; column 13, lines 15-33);

adjusting the initial baseline value by factoring in cost offsets due to inflation and technological advances to establish a prospective cost for the decided course of treatment, and by factoring in one or more historically derived severity factors to derive an adjusted baseline value (Kessler; column 13, lines 15-33); Examiner interprets Kessler's teachings of "the limit can be adjusted for different geographic areas and for different types of medical care providers to reflect

differences in costs" (Kessler; column 13, lines 20-22) to be a form of factoring in cost offsets due to diverse variables and consequently as reading on this limitation; and

for purposes of improving utilization of healthcare services in the decided course or treatment relative to utilization of healthcare services quantified by the initial baseline value (Bitran; page 15; lines 1-18); Examiner interprets Bitran's teachings of using incentives in order to improve efficiency (Bitran; page 15, lines 15-18) as reading on this limitation.

The remainder of claim 1 is rejected for the same reasons given in the prior Office Action (paper number 03242005, section 6, pages 5-6), and incorporated herein.

The motivations to combine the respective teachings of Kessler and Bitran are as discussed in the prior Office Action (paper number 03242005), and incorporated herein.

(B) Claim 2 has been amended to include the recitation of

- "[...] the decided course of treatment is selected from the group consisting of diagnostic tests, prescribed drugs, practitioner office visits professional fees, equipment operating costs, and medical procedures; and wherein the healthcare services comprise at least one of diagnostic tests, drug prescriptions, subsequent hospital visits and additional practitioner diagnosis, [...]" at lines 4-9.

As per these new limitations, Kessler and Bitran teach a method as analyzed and discussed in the previous Office Action (paper number 03242005) wherein

the decided course of treatment is selected from the group consisting of diagnostic tests, prescribed drugs, practitioner office visits professional fees, equipment operating costs, and medical procedures; and wherein the healthcare services comprise at least one of diagnostic

tests, drug prescriptions, subsequent hospital visits and additional practitioner diagnosis (Kessler; column 6, lines 40-51, column 13, lines 15-33); Examiner interprets Kessler's teachings of "a medical care provider can quickly provide a comprehensive summary of the areas of the patient's body which have been treated during a given visit, as well as pertinent diagnostic information" (Kessler; column 6, lines 47-50) as teaching this limitation.

The remainder of claim 2 is rejected for the same reasons given in the prior Office Action (paper number 03242005, section 6, pages 6-7), and incorporated herein.

The motivations to combine the respective teachings of Kessler and Bitran are as discussed in the prior Office Action (paper number 03242005), and incorporated herein.

(C) Claim 3 has been amended to include the recitation of

- "[...] payer comprises an insurance company, and wherein the initial baseline value is derived from historical data relating to normal operating policies of the insurance company, [...]" at lines 4-6.

As per these new limitations, Kessler and Bitran teach a method as analyzed and discussed in the previous Office Action (paper number 03242005)

wherein the payer comprises an insurance company (Kessler; column 4, lines 28-33, column 8, lines 29-33, column 14, lines 49-64), and wherein the initial "dollar limit" (reads on "baseline value") is derived from historical data relating to normal operating policies of the insurance company (Kessler; column 13, lines 15-33, column 14, lines 48-55).

The remainder of claim 3 is rejected for the same reasons given in the prior Office Action (paper number 03242005, section 6, page 7), and incorporated herein.

The motivations to combine the respective teachings of Kessler and Bitran are as discussed in the prior Office Action (paper number 03242005), and incorporated herein.

(D) Claim 7 has been amended to include the recitation of

- "[...] the severity factors include at least one of the age of the patient, pre-existing conditions of the patient, comorbidity effects, drug interactivity, presence of diagnosis codes and defining procedures [...]" at lines 4-9.

As per these new limitations, Kessler and Bitran teach a method as analyzed and discussed in the previous Office Action (paper number 03242005)

wherein the severity factors include the presence of diagnosis codes (Kessler; column 6, lines 40-2, column 8, lines 58-61, column 13, lines 15-34); Examiner interprets Kessler's teachings of "for more costly medical care providers, such as neurosurgeons, the medical data draft could have a different limit than for less costly providers, such as pediatricians ... method and apparatus of this invention provides for such flexibility by both geography and the type of medical care provided" (Kessler; column 13, lines 28-34) as teaching "severity factors."

The remainder of claim 7 is rejected for the same reasons given in the prior Office Action (paper number 03242005, section 6, page 7), and incorporated herein.

The motivations to combine the respective teachings of Kessler and Bitran are as discussed in the prior Office Action (paper number 03242005), and incorporated herein.

(E) The amendments to claim 16 appear to have been made merely to change dependencies and to correct minor typographical or grammatical errors. While these changes

render the language of the claim smoother and more consistent, they otherwise affect neither the scope and breadth of the claim as originally presented nor the manner in which the claim was interpreted by the Examiner when applying prior art within the previous Office Action.

As such, the recited claimed features are rejected for the same reasons given in the prior Office Action (paper number 03242005, section 6, pages 7-8), and incorporated herein.

The motivations to combine the respective teachings of Kessler and Bitran are as discussed in the prior Office Action (paper number 03242005), and incorporated herein.

(F) Apparatus claim 55 repeats the subject matter of claim 1, respectively, as a set of "means-plus-function" elements rather than a series of steps. As the underlying processes of claim 1 have been shown to be obvious in view of the teachings of Kessler and Bitran in the above rejections of claim 1, it is readily apparent that the system disclosed by Kessler and Bitran includes the apparatus to perform these functions. As such, these limitations are rejected of the same reasons given above for method claim 1, and incorporated herein.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler et al., U.S. Patent Number 5, 324, 077 in view of Bitran, et al, Provider Incentives and Productive Efficiency in Government Health Services document, September, 1992. URL: <http://www.phrplus.org/Pubs/hfsmar1.pdf>, hereinafter known as Bitran, as applied to claim 1 above, and further in view of Spiro, U.S. Patent Number 5, 819, 228 for substantially the same reasons as in the previous Office Action (paper number 03242005). Further reasons appear hereinbelow.

(A) Claim 8 has been amended to include the recitation of

- "[...] during the treatment of the patient for the condition during the episode of care the patient encounters an additional condition that creates another episode of care and the step of adjusting the initial baseline value further includes the step of factoring in the additional condition, [...]" at lines 2-5.

As per newly amended claim 8, Kessler, Bitran and Spiro teach a method as analyzed and disclosed above

wherein during the treatment of the patient for the condition during the episode of care the patient encounters an additional condition that creates another episode of care and the step of adjusting the initial baseline value further includes the step of factoring in the additional condition or "other parameters" (Spiro; column 2, line 47 to column 3, line 30, column 7, lines 15-55, column 9, line 14 to column 10, line 25).

The remainder of claim 8 is rejected for the same reasons given in the prior Office Action (paper number 03242005, section 7, pages 8-10), and incorporated herein.

The motivations to combine the respective teachings of Kessler, Bitran and Spiro are as discussed in the prior Office Action (paper number 03242005), and incorporated herein.

9. Claims 9 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler et al., U.S. Patent Number 5, 324, 077 and Bitran, et al, Provider Incentives and Productive Efficiency in Government Health Services document, September, 1992. URL: <http://www.phrplus.org/Pubs/hfsmar1.pdf>, hereinafter known as Bitran as applied to claims 1, 3, and 16 above, and further in view of Seare, U.S. Patent Number 5, 557, 514.

(A) Claim 9 has been amended to include the recitation of

- "[...] the process of adjusting the initial baseline value by factoring in one or more historically derived severity factors comprises applying one or more business rules quantifying how the severity factors affect treatment costs for the condition [...]" at lines 2-4.

As per newly amended claim 9, Kessler and Bitran teach a method as analyzed and disclosed in claim 1 above.

Kessler and Bitran fail to explicitly disclose a method

wherein the process of adjusting the initial baseline value by factoring in one or more historically derived severity factors comprises applying one or more business rules quantifying how the severity factors affect treatment costs for the condition.

However, the above features are well-known in the art, as evidenced by Seare.

In particular, Seare teaches a method

wherein the process of adjusting the initial baseline value by factoring in one or more historically derived severity factors comprises applying one or more "logic" adjustments (reads on "business rules") quantifying how the severity factors affect treatment costs for the condition (Seare; column 13, lines 22-24, column 13, line 55 to column 14, line 35, column 21, line 61 to column 22, line 3, column 27, lines 52-57).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the collective teachings of Kessler and Bitran to include the added limitations, as taught by Seare, with the motivations of analyzing historical medical provider

billings to statistically establish a normative profile, enabling comparison of a medical provider's profile with a normative profile, creating an accurate model of the cost of a specific medical episode based on historical treatment patterns and a fee schedule, enabling comparison of various treatment patterns for a particular diagnosis by treatment cost and patient outcome to determine the most cost-effective treatment approach, and identifying those medical providers who provide treatment that does not fall within the statistically established treatment patterns or profiles (Seare; Abstract).

The motivations to combine the respective teachings of Kessler and Bitran are as discussed in the prior Office Action (paper number 03242005), and incorporated herein.

(B) As per newly amended claim 17, Kessler and Bitran teach a method as analyzed and discussed in claims 1, 3, and 16 above. Kessler and Bitran fail to explicitly disclose a method wherein prior to the step of creating the initial baseline is the step of filtering to remove outlier episodes of care for the same condition to thereby establish the plurality of data relating to a plurality of previous episodes of care for the same condition.

However, the above features are well-known in the art, as evidenced by Seare.

In particular, Seare teaches a method including the step of filtering to remove outlier episodes of care (Seare; see at least Figure 14, column 4, lines 39-43, column 8, line 49 to column 9, line 20, column 12, lines 49-67, column 21, lines 37-43, column 24, lines 3-12).

The motivations to combine the respective teachings of Kessler, Bitran and Seare are as discussed in the prior Office Action (paper number 03242005), and in claim 9 above, and incorporated herein.

Response to Arguments

10. Applicant's arguments filed 3 October 2005 and 15 August 2005 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 15 August 2005.

At pages 8-10 of the 15 August 2005 response Applicant argues that the features in the Application are not taught or suggested by the applied references. In response, all of the limitations which Applicant disputes as missing in the applied references, including the newly added features in the 3 October 2005 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Kessler, Bitran Spiro, and Seare, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action (paper number 03242005), and incorporated herein. In particular, Examiner notes that the recited features of an initial baseline value related to treatment of the condition and adjustment of this initial baseline value are taught by the combination of applied references. In particular, please note that Examiner interprets Kessler's teachings of "the limit can be adjusted for different geographic areas and for different types of medical care providers to reflect differences in costs" (Kessler; column 13, lines 20-22) to be a form of factoring in cost offsets due to diverse variables and consequently as reading on this limitation.

With regard to Applicant's argument in the last paragraph of page 8 in the 5 August 2005 response that "Bitran ... [...] ... does not teach or suggest ... payments that are individually calculated based on specific episodes of care," Examiner respectfully notes that this is not a claimed limitation.

With regard to Applicant's argument in the first paragraph of page 9 in the 5 August 2005 response that Bitran does not teach or suggest causing a portion of the cost savings to be sent to the healthcare provider in the form of the monetary incentive for purposes of improving utilization of healthcare services in the decided course or treatment relative to utilization of healthcare services quantified by the initial baseline value and "the used of targeted incentives to alter utilization patterns," Examiner respectfully disagrees. Examiner notes that Bitran teaches sending monetary incentives to healthcare providers (Bitran; page 31, paragraph 4) and additionally interprets Bitran's teachings of using incentives in order to improve efficiency (Bitran; page 15, lines 15-18) as reading on these limitations.

Conclusion

11. Any response to this action should be mailed to:

Commissioner of Patents and Trademarks
Washington D.C. 20231

or faxed to: **(571) 273-8300.**

For informal or draft communications, please label "PROPOSED" or "DRAFT" on the front page of the communication and do NOT sign the communication. After Final communications should be labeled "Box AF."

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Pass whose telephone number is (571) 272-6774. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 6:30 PM. The examiner can also be reached on alternate Fridays.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (571) 272-3600.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NP

Natalie A. Pass

December 27, 2005

HYUNG SOUGH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600